Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 725.1046

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/533,942	May 4, 2005

First Named Inventor: Garaci, E.

Art Unit	Examiner
1628	Zarek, P.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 48,265.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Silvia Salvadori/
Signature

Silvia Salvadori
Typed or printed name

646-783-6758
Telephone number

February 23, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Docket No.: 725.1046

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Garaci, et al. Confirmation No.: 9693

Serial No. : 10/533,942

Filed : May 4, 2005

Art Unit : 1628

Examiner : Zarek, P.E.

For : **USE OF RESVERATROL FOR THE PREPARATION OF A MEDICAMENT USEFUL FOR THE TREATMENT OF INFLUENZA VIRUS INFECTIONS**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Pre-Appeal Brief

Sir:

Applicants submit the Pre-Appeal Brief, together with a Notice of Appeal in the above-identified application.

REMARKS

All of the pending claims 4-9 and 13-18 are the subject of Applicants' appeal.

The presently claimed invention is directed to:

A method of inhibiting influenza virus replication comprising
administering to a subject having an influenza virus infection an amount of resveratrol which inhibits influenza virus replication and does not inhibit influenza virus target cell entry. (Emphasis added).
(*e.g.*, from page 8 line 23, to page 9 line 14, figures 3, 4A and 4B).

The Examiner has rejected the pending claims under (1) 35 U.S.C. § 103(a) for allegedly being obvious over Root et al. (Journal of General Virology, 2000, hereinafter "Root") in view of Stewart et al. (Biochemistry, 1999, hereinafter "Stewart") and Heredia et al. (Journal of Acquired Immune Deficiency Syndromes, 2000, hereinafter "Heredia"); and (2) under 35 U.S.C. § 112, ¶ 1, for allegedly failing to comply with the written description requirement.

Rejection under 35 U.S.C. § 103(a)

As previously submitted, Root does not disclose Applicants' invention but only provides for a PKC inhibitor bisindolylmaleimide I.HCl which inhibits viral cell entry and blocks the infection differently from the protein kinase inhibitor H7 (*e.g.*, page 2701, lines 10- 13, 14-17 and 48-51 and page 2699, right col., lines 46-49). Thus, Root does not disclose all of the claimed limitations which specifically indicate that the resveratrol does not inhibit influenza virus target cell entry and teaches that PKC inhibitors have different mechanisms.

Stewart also does not disclose Applicants' claimed subject matter and does not make up for Root's deficiencies. Stewart only describes that resveratrol is a cancer chemopreventive agent that antagonizes each stage of carcinogenesis and that weakly inhibits protein kinase C (*e.g.*, page 13249, right col., lines 1-3 and 24-26). Moreover,

Stewart is completely silent with regard to presently claimed subject matter. Thus, Stewart as well does not disclose all of the claimed limitations.

Heredia also does not teach Applicants' claimed invention and does not correct Root's and Stewart's defects. Heredia teaches that resveratrol together with zidovudine synergistically inhibits HIV replication (*e.g.*, summary, lines 3-5). However, the teachings and the results obtained on HIV-1 are non-transferable to influenza virus. Thus, Heredia does not provide any motivation to use resveratrol to arrive at the presently claimed subject matter.

Moreover, Applicants respectfully assert that the Examiner's reasoning on page 3-4 of the Office Action is incorrect. Root specifically describes that bisindolylmaleimide does inhibit virus cell entry. Stewart, according to the Examiner, suggests that a dose of resveratrol of 3.4 μg/ml prevents the virus from entering the cells.

However the present specification clearly discloses that a concentration of 20 μg/ml ml of resveratrol does not inhibit virus target cell entry. Root clearly teaches that PKC inhibitors are not comparable and nothing, from the teachings of Root and Stewart, provides any hint or motivation that 3.4 μg/ml of resveratrol could inhibit influenza virus target cell entry. In addition, Heredia's teachings that resveratrol is a low cost drug with an established safety profile not only are completely irrelevant but also do not provide a motivation for choosing a cancer chemoprotective agent for inhibiting influenza virus replication.

Thus, the Examiner's conclusion that the art suggests using a dose of resveratrol that inhibits the replication but not the entry of the virus into the cells is incorrect and based on impermissible hindsight.

Accordingly, it is respectfully submitted that the combination of the cited references would not have rendered obvious the claimed subject matter.

Rejection under 35 U.S.C. § 112, ¶ 1

On page 5, lines 2-11, the Office Action has indicated that the amended claims contain new matter and that the specification fails to discuss at which doses resveratrol inhibits influenza virus replication without inhibiting target cell entry.

As an initial matter, the standard to satisfy the written description requirement is that a patent specification must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). Thus, the specification does not have to disclose, either implicitly or explicitly that only specific doses of resveratrol inhibit influenza virus replication without inhibiting the virus target cell entry.

The specification discloses that a dose of 20 μg/ml of resveratrol is capable of inhibiting the virus replication but not the target cell entry. Thus, it sufficiently shows to those skilled in the art that the Applicants were in possession of the claimed invention.

Further, the claim should not be rejected or objected to on the ground of new matter. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). The concept of new matter is properly employed as a basis for objection to amendments to the abstract, specification or drawings attempting to add new disclosure to that originally presented.

While the test or analysis of description requirement and new matter issues is the same, the examining procedure and statutory basis for addressing these issues differ. Thus, this Examiner's rejection is based on an incorrect standard.

Moreover, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). In other words, the examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Applicants respectfully submit that the Examiner has not met his burden. The specification discloses that 20 μg/ml of resveratrol are capable of inhibiting influenza virus replication without affecting the entry of the virus into a target cell. Applicants are not required to show different ranges of resveratrol to prove this irrefutable effect. Thus, for all of these reasons, Applicants respectfully submit that the claims comply with the written description requirement because they contain subject matter described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

For all of the reasons set forth above, the Examiner's rejection under 35 U.S.C. § 103 (a) and under 35 U.S.C. § 112, ¶ 1, are untenable and should be overturned.

Respectfully submitted

Date: February 23, 2011

LUCAS & MERCANTI, LLP

By: /Silvia Salvadori/

Silvia Salvadori, Reg. No. 48,265
475 Park Avenue South
New York, NY 10016
Phone: (646) 783-6758
Fax: (212) 661-8002